

National Cancer Institute
Institutional Review Board

AGENDA
June 22, 2015
1:00 – 5:00 pm
10 CRC/3-1608

1. **Review of Draft Minutes, June 8, 2015**
2. **Announcements**
3. **Old Business**
4. **New Business**
5. **Problem Report Forms**
6. **Other Expedited Actions**
7. **Continuing Reviews**
8. **Response to Stips** 12C0008-F, "An Open Label Phase I Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose of the Antimesothelin Antibody Drug Conjugate BAY 94-9343 in Subjects with Advanced Solid Tumors" - Raffit Hassan, PI
9. **Amendment** 02C0210-R, ""Clinical, Laboratory, and Epidemiologic Characterization of Individuals and Families at High Risk of Blood and Lymph Node Malignancy"" - Neil Caporaso, PI
10. **Amendment** 11C0061-K, "Phase I Trial of Z-Endoxifen in Adults With Refractory Hormone Receptor-Positive Breast Cancer, Desmoid Tumors, Gynecologic Tumors, or Other Hormone Receptor-Positive Solid Tumors" - Alice Chen, PI
11. **Amendment** 15C0029-B, "Phase I Dose Escalation Study of Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults with Recurrent or Refractory CD22-expressing B Cell Malignancies" - Terry Fry, PI
12. **Amendment** 13C0202-B, "Tissue Procurement and Natural History Study of Patients with Malignant Mesothelioma and Other Mesothelin Expressing Cancers" - Raffit Hassan, PI
13. **Amendment** 13C0193-G, "Evaluation of 68Gallium- DOTATATE PET/CT for Detecting Primary and Metastatic Neuroendocrine Tumors" - Electron Kebebew, PI
14. **Amendment** 09C0082-Y, "Assessment of the Safety and Feasibility of Administering T cells Expressing an anti-CD19 Chimeric Antigen Receptor to Patients with B-cell Lymphoma" - Steve Rosenberg, PI
15. **Amendment** 11C0161-I, "A Phase I/II Study of the Mitogen Activated Protein Kinase Kinase (MEK) 1 Inhibitor Selumetinib (AZD6244; Hydrogen Sulfate in Children with Neurofibromatosis Type 1 (NF1) and Inoperable Plexiform Neurofibromas (PN)" - Brigitte Widemann, PI

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AGENDA (*continued*)

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| 16. Initial Review | P141617, "Phase II Trial of the MEK1/2 Inhibitor Selumetinib (AZD6244 Hydrogen Sulfate in Adults with Neurofibromatosis Type 1 (NF1) and Inoperable Plexiform Neurofibromas" - Brigitte Widemann, PI |
| 17. Initial Review | P152249, "A Phase I Trial of Pomalidomide for Children with Recurrent, Progressive or Refractory CNS Tumors" - Kathy Warren, PI |
| 18. Initial Review | P152261, "A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0011359C in Subjects with Metastatic or Locally Advanced Solid Tumors with Expansion to Selected Indications" - James Gulley, PI |
| 19. Initial Review | P152259, "A Phase Ib, Dose Escalation, Multiple Dose Trial with HuMax-IL8 in Patients with Metastatic or Unresectable, Locally Advanced Malignant Solid Tumors" - Christopher Heery, PI |